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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,400	FRUDAKIS ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- Th MAILING DATE of this communication app ars on th cov r she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4, 8, 11-in-part (b), and 15, drawn to isolated polynucleotides, kits, and compositions comprising those polynucleotides, vectors, and transformed host cells, classified in class 536, subclass 23.1.

II. Claims 2, 7, 11-in-part (a) and (d), drawn to polypeptides, fusion proteins, and compositions comprising the peptides, classified in class 530, subclass 350.

III. Claims 5, 11-in-part (c), and 16 drawn to antibodies, classified in class 530, subclass 388.1.

IV. Claim 6, drawn to a method of detecting cancer using a peptide binding agent, classified in class 435, subclass 7.1+.

V. Claim 9-in-part (a), drawn to a method of stimulating and/or expanding a T cell population using a polypeptide, classified in class 424, subclass 184.1.

VI. Claim 9-in-part (b), drawn to a method of stimulating and/or expanding a T cell population using a polynucleotide, classified in class 514, subclass 44.

VII. Claim 9-in-part (c), drawn to a method of stimulating and/or expanding a T cell population using antigen presenting cells, classified in class 424, subclass 93.7.

VIII. Claims 10 and 11-in-part (e), drawn to isolated T cells, classified in class 424, subclass 93.71.

IX. Claim 11-in-part (f), drawn to isolated antigen presenting cells, classified in class 424, subclass 93.71.

X. Claim 12-in-part (a) and (d), drawn to a method of stimulating an immune response in a patient using a polypeptide, classified in class 424, subclass 184.1.

XI. Claim 12-in-part (b), drawn to a method of stimulating an immune response in a patient using a polynucleotide, classified in class 514, subclass 44.

XII. Claim 12-in-part (c), drawn to a method of stimulating an immune response in a patient using an antibody, classified in class 424, subclass 130.1.

XIII. Claim 12-in-part (e), drawn to a method of stimulating an immune response in a patient using isolated T cells, classified in class 424, subclass 93.71.

XIV. Claim 12-in-part (f), drawn to a method of stimulating an immune response in a patient using antigen presenting cells, classified in class 424, subclass 93.71.

XV. Claim 13-in-part (a) and (d), drawn to a method of treating cancer in a patient using a polypeptide, classified in class 424, subclass 184.1.

XVI. Claim 13-in-part (b), drawn to a method of treating cancer in a patient using a polynucleotide, classified in class 514, subclass 44.

XVII. Claim 13-in-part (c), drawn to a method of treating cancer in a patient using an antibody, classified in class 424, subclass 130.1.

XVIII. Claim 13-in-part (e), drawn to a method of treating cancer in a patient using isolated T cells, classified in class 424, subclass 93.71.

XIX. Claim 13-in-part (f), drawn to a method of treating cancer in a patient using antigen presenting cells, classified in class 424, subclass 93.71.

XX. Claim 14, drawn to a method of detecting cancer using an oligonucleotide, classified in class 435, subclass 6.

XXI. Claim 17-in-part, drawn to a method of inhibiting cancer in a patient using a polypeptide, classified in class 424, subclass 184.1.

XXII. Claim 17-in-part, drawn to a method of inhibiting cancer in a patient using antigen presenting cells, classified in class 424, subclass 93.71.

XXIII. Claim 17-in-part, drawn to a method of inhibiting cancer in a patient using polynucleotides, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a polypeptide of group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examiner together, as compared to being searched separately. Also, it is pointed out

that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and III are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claim of group III is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention III would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Inventions I and IV, V, VII, X, XII, XIII, XIV, XV, XVII, XVIII, XIX, XXI and XXII are separate and distinct as the polynucleotides of Invention I are not used in the polypeptide based assays and methods, antibody based assays and methods, T cell based assays and methods, and APC based assays and methods of the other listed inventions. The Inventions would each require searching separate and non-overlapping areas which would constitute an undue search burden on the examiner if not restricted.

Inventions I and VI, XI, XVI and XX and XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used to express a recombinant protein, and can be used in PCR methods for detection of that sequence in a sample.

Inventions I and VIII/ IX are unrelated as they are differing compositions of matter. Invention I is drawn to isolated polynucleotides, while Inventions VIII and IX are drawn to isolated cell populations which comprise a great variety of biological compounds. As such, it would pose an undue burden to search and examine these inventions if not restricted.

Inventions II and III are separate and distinct as the polypeptides of Invention II are structurally and biochemically different than the antibodies of Invention III. While the antibodies may bind to the polypeptides of Invention II, the biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions II and IV, VI, VII,XI, XII, XIII, XIV, XVI, XVII, XVIII, XIX, XX and XXII are separate and distinct as the polypeptides of Invention II are not used in the methods of the other listed Inventions. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions II and V, X, XV and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in expression profiles.

Inventions II and VIII/ IX are unrelated as they are differing compositions of matter. Invention I is drawn to isolated polypeptides, while Inventions VIII and IX are drawn to isolated cell populations which comprise a great variety of biological compounds. As such, it would pose an undue burden to search and examine these inventions if not restricted.

Inventions III and VIII/ IX are separate and distinct as the antibodies of Invention III are structurally and biochemically different than the isolated cell types of inventions VIII and IX. The biochemical activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Inventions III and V, VI, VII, X, XI, XIII, XIV, XV, XVI, XVIII, XIX, XX, XXI and XXII and XXIII are separate and distinct as the antibodies of Invention III are not used in the methods of the other listed Inventions. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions III and IV, XII, and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used to purify expressed polypeptides to which they bind.

Invention VIII is separate and distinct from Invention IX as they are drawn to differing types of isolated cell populations, each having particular definitions and differing types of

activities. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions VIII and IV, VI, VII, X, XI, XII, XIV, XV, XVI, XVII, XIX, XX, XXI and XXII and XXIII are separate and distinct as the isolated T cells of Invention VIII are not used in the methods of the other listed Inventions. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions VIII and XIII, and XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated T cells can be used in *in vitro* immune cell activation studies.

Inventions IX and IV, VI, X, XI, XII, XIII, XV, XVI, XVII, XVIII, XX, and XXI and XXIII are separate and distinct as the APC's of Invention IX are not used in the methods of the other listed Inventions. As such the Inventions would require search in separate and non-overlapping areas, imposing an undue search burned upon the examiner if not restricted.

Inventions IX and VII, XIV, XIX and XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated APC's can be used in *in vitro* immune cell activation studies.

The polypeptide-based methods of inventions V, X, XV and XXI are each separate and distinct from one another as they are differing methods, having differing goals, differing intended outcomes and differing steps. The differing inventions also carry differing burdens of enablement and description such that the search and examination of more than one method would pose an undue burden upon the examiner, if not restricted.

The polynucleotide-based methods of inventions VI, XI, XVI, and XX and XXIII are each separate and distinct from one another as they are differing methods, having differing goals,

differing intended outcomes and differing steps. The differing inventions also carry differing burdens of enablement and description such that the search and examination of more than one method would pose an undue burden upon the examiner, if not restricted.

The antibody-based methods of inventions IV, XII, and XVII are each separate and distinct from one another as they are differing methods, having differing goals, differing intended outcomes and differing steps. The differing inventions also carry differing burdens of enablement and description such that the search and examination of more than one method would pose an undue burden upon the examiner, if not restricted.

The T cell-based methods of inventions XIII and XVIII are each separate and distinct from one another as they are differing methods, having differing goals, differing intended outcomes and differing steps. The differing inventions also carry differing burdens of enablement and description such that the search and examination of more than one method would pose an undue burden upon the examiner, if not restricted.

The APC-based methods of inventions VII, XIV, XIX and XXII are each separate and distinct from one another as they are differing methods, having differing goals, differing intended outcomes and differing steps. The differing inventions also carry differing burdens of enablement and description such that the search and examination of more than one method would pose an undue burden upon the examiner, if not restricted.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to or using amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to or using nucleotide sequences, the Applicants must elect a single polynucleotide sequence. For an elected group drawn to or using antibodies, Applicant must elect a single sequence to which the antibody is to be specific. For an elected group drawn to a cell population expressing a polypeptide, a single sequence must be elected.

Nucleotide sequences encoding different proteins are structurally distinct chemical

compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. In view of Office Resources, the search and examination of more than one sequence would pose an undue burden upon the office, therefore, Applicant must elect a single sequence to be searched. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Due to the complexity of the restriction requirement, no telephone election was attempted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A fully responsive reply to this requirement will elect both an Invention and a particular sequence, as required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
9/25/02

MARY K. ZEMAN
PRIMARY EXAMINER
AU 1631